510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002647

Applicant information:

Date Prepared:	August 21, 2000
Name: Address	Marietta Contact Lens Service 128 Cherry Street Marietta, GA 30060
Contact Person: Phone Number:	Mr. John Patterson President (770) 792-0208
USA Consultant:	Martin Dalsing, Med-Vice Consulting, Inc. Consultant for Marietta Contact Lens Service 623 Glacier Drive Grand Junction, CO 81503 (970) 243-5490 Fax #: (970) 243-5501 E-mail: mdalsing@gj.net

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Trade Name:	**Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact lens for Daily Wear**
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The "Marietta Contact Lens Service" tinted soft contact lens is substantially equivalent to the DURASOFT 2 COLORS tinted soft contact lens, and the Colorsoft, Color Enhanced Tinted Soft Contact Lens for Daily Wear predicate devices.

INDICATIONS FOR USE:

The Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color. The Marietta Contact Lens Service visibility-handling tint provides for ease of patient handling and does not affect iris color.

Except for decreased light transmittance due to the tint intensity, the pre-tinted lens optical parameters remain the same as originally prescribed for the user prior to tinting. The lens is to be disinfected according to the original lens manufacturer's recommendation.

Device Descriptive Characteristics:

Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact Lens are color enhanced soft contact lenses that have been previously prescribed for a specific patient. They have been supplied to Marietta Contact Lens Service to be modified by a tinting process. The color additives have been listed as safe for contact lenses in accordance with the FDA's color additive regulations. The color additives are used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris. The Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact Lens is available in a light, medium or dark shade of the following enhance colors: Blue, Sky Blue, Green, Aquamarine, Yellow, Violet, Red, Brown, Black and Amber. Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact Lens are also available in a standard blue visibility-handling tint.

The color additive effect is formed by the reaction of one or more of the reactive color additives listed in this paragraph with (poly hydroxyethyl methacrylate). The reactive color additives that may be used either alone or in combination are: reactive black 5, reactive blue 21, reactive blue 19, reactive blue 4, reactive blue 163, reactive red 11, reactive red 180, reactive yellow 15, reactive yellow 86, or reactive orange 78. The color additives used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens.

The tint patterns available to the practitioner:

- Clear Pupil diameter (2.5mm and 4.5mm).
- Annular (iris) diameter (10.5mm and 11.5mm), standard is 11.5mm diameter.
- Black pupil diameter (3mm to 11.5mm), standard is 4.0mm diameter.

The following table summarizes Marietta Contact Lens Service claim of substantial equivalency in terms of safety and efficacy to the predicate devices previously mentioned.

	Characteristic	Marietta Contact Lens Service Tinted Soft Contact Lens	Predicate Device
1.)	INTENDED USE	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
2.)	INDICATION	The Marietta Contact Lens Service, Colored Enhanced Tinted Soft Contact Lenses for daily wear are indicated for enhancing and/or altering the apparent eye color. The Marietta Contact Lens Service visibility tint provides for ease of patient handling and does not effect iris color. The lens is to be disinfected following the original manufacturer's instructions.	The Durasoft 2 Colors for daily wear are indicated for enhancing and/or altering the apparent eye color, including ocular masking. The Colorsoft, Color Enhanced Tinted Soft Contact Lens for Daily Wear are indicated for enhancing and/or altering the apparent eye color. Visibility tint provides ease of patient handling and does not effect iris color.
3.)	ACTIONS	In its hydrated state, when placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.	In its hydrated state, when placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.
4.)	FDA "listed" colored additives	The reactive colored additives consist of reactive black 5, reactive blue 4, reactive blue 19, reactive 21, reactive blue 163, reactive yellow 15, reactive yellow 86, reactive orange 78, reactive red 11 and reactive red 180.	The Durasoft 2 Colors colored pigments consist of iron oxides, chromium oxide greens, titanium dioxide, [phthalo-cyaninato (2-)] copper, carbazole violet and phthalocyanine green. The Colorsoft, Color Enhanced Tinted Soft Contact Lens for Daily Wear consist of reactive black 5, reactive blue 4, reactive blue 19, reactive 21, reactive blue 163, reactive yellow 15, reactive yellow 86, reactive orange 78, reactive red 11 and reactive red 180
a.	Uses and restrictions	The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accompish the intended coloring effect.	The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accompish the intended coloring effect.
5.)	Color Additive Characteristics	The color additives used are not removed by lens handling and cleaning/disinfecting procedures. The optical and performance characteristics are not altered by the lens coloring process.	The color additives used are not removed by lens handling and cleaning/disinfecting procedures. The optical and performance characteristics are not altered by the lens coloring process.
6.)	Colors Offered	Blue, Sky Blue, Green, Aquamarine, Yellow, Violet, Red, Chocolate, Black and Amber	The Durasoft 2- Sky blue, Jade green, Aquamarine and Violet blue The Colorsoft, Color Enhanced Tinted Soft Contact Lens for Daily Wear- Blue, Deep Blue, Green, Aquamarine, Yellow, Violet, Red, Chocolate, Black and Amber

Table #1 – Substantial Equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 2000

Mr. Martin Dalsing
Consultant for Marietta Contact Lens Service
C/O Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K002647
Trade Name: Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact Lens for Daily Wear.
Regulatory Class: II
Product Code: LPL
Dated: August 21, 2000
Received: August 24, 2000

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **Marietta Contact Lens Service, Color Enhanced Tinted Soft Contact lens for Daily Wear**

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(PLEASE DO OT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph D
(Division Sign-Off)
Division of Ophthalmic Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K002647

Over-The-Counter Use ___

(Optional Format 1-2-96)